



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219
23117 7590 02/15/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 167 and 177-179 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 167 and 177-179 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 11/14/2006.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 167, 177, and 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'101.

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Tissue compatibility although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. The amount of drug distributed

Art Unit: 1615

through the implant, the depth of impregnated bioactive, as well as the amount of resorption are dependent upon the material and its porosity. Since the reference discloses both, these parameters are inherent to the material selected. As stated there, since silicon in general works, any silicon-based compound which has similar corrosion properties and is not harmful can read in the claimed silicon product. As such, the silicon product of WO'101 falls well within this definition. As such, the ordinary practitioner would have expected similar therapeutic results from using the porous silicon of WO'101. The instant claim would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of WO'101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 167, 172 are rejected under 35 U.S.C. 102(b) as being anticipated by WO'97/06101 (WO'101).

Art Unit: 1615

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Tissue compatibility although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. The amount of drug distributed through the implant, the depth of impregnated bioactive, as well as the amount of resorption are dependent upon the material and its porosity. Since the reference discloses both, both of these parameters are inherent to the material selected. The instant claims are anticipated by WO'101.

Response to Arguments

Applicant's arguments filed 11/14/2006 have been fully considered but they are not persuasive.

Applicant does not argue specifically against either the rejection under 35 USC 102(b) or 35 USC 103(a), but makes a generic statement directed to both. Applicant argues that the reference does not disclose the specific embodiment of phosphorus between 1 and 90 percent and at the specific depth of 0.35 and 1000 microns without addressing the point of either rejection. Specifically, the rejection under 35 USC 103(a) states that since the reference discloses the same mesoporous silicon, that the concentration of bioactive as well as its placement would be determined by the characteristics of that material selected; in this case silicon. So that even if applicant

Art Unit: 1615

has now selected the depth of the phosphorus which is to be impregnated, this depth would be determined by the porosity, which is in turn selected by the particular material selected; in this case, the same mesoporous silicon. No statement is made as why one of ordinary skill at the time of invention would not have expected similar therapeutic results from the instantly claimed implant or why the instant implant is not anticipated by the WO'101 reference.

Further it is not understood how the reference teaches away from the instantly claimed invention given that it also discloses the inclusion of phosphorous into its implant. Applicant cites the teaching of tissue compatibility, and this examiner must point to the teaching at page 23 which also teaches greater bioactivity. This would appear to support the rejection cited rather than teach away from them.

The rejections under 35 USC 102(b) and 35 USC 103(a) are therefore maintained.

The following are new rejections made in response to the amendments to the claims:

Claim Rejections - 35 USC § 112

Claims 167, 177-179 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

Art Unit: 1615

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While applicant points to drawing 5 for support of the disclosure of essential elements being delivered, the drawing makes a general statement concerning the highlighted elements as "essential trace elements and/or having deficiency problems". However, there is no specific embodiment described which sets out phosphorus as an element to be delivered by the implant. As such, this is unsupported by the original specification.

Likewise, claim 179 is not supported by the original specification in that no where does the original specification set out this embodiment.

Regarding claim 178, the specification does not support the limitation that the largest dimension is between 0 and 2 mm. Indeed, at page 5, lines 15-25, a dimension of 20 mm is recited. No support could be found for limiting the size to the claimed range.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 167 and 177 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 167 sets out that the essential element to be incorporated into the implant is phosphorus, and claim 177 which depends on it, broadly sets out all essential elements. As such, applicant is improperly setting out a broad claim as dependent upon a narrow species claim. The metes and bounds of the invention are therefore indefinite. Appropriate correction is requested.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

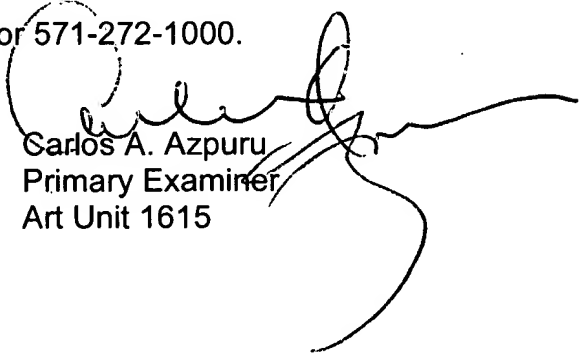
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca